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EXAMINER	
TRAN, MY CHAU T	
ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/991,610	Applicant(s) HANNAH, ERIC C.	
	Examin r My-Chau T. Tran	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *14-20 and 31-48* is/are pending in the application.

4a) Of the above claim(s) *40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-20,31-39 and 41-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment filed 1/23/03 in Paper No. 7 is acknowledged and entered. Claims 1-13 and 21-30 are canceled by the amendment. Claims 31-48 are added by the amendment.

2. Claims 14-20 and 31-48 are pending.

Election/Restrictions

3. Applicant's election without traverse of Group III (Claims 14-20) in Paper No. 7 is acknowledged. The election is considered without traverse because applicant cancellation of claims 1-13 and 21-30, which are drawn to non-elected inventions.

4. Applicant's species election with traverse in Paper No. 9 is acknowledged. The elected species are follows:

a) Specific species of ligand of Claim 20: nucleic acid.

b) Type of probe (Group A): chemically modified oligonucleotide.

c) Length of probe (Group B): 6.

The traversal is on the ground(s) that there is no patentably distinction of the species election of ligand specifically between nucleic acid, polynucleotide, and oligonucleotide. Applicant state that these "species are chemically identical and the only distinction being one of length" (see response, pg. 2, lines 6-8). Applicant traverses the species election requirement with respect to type of probe on the ground that the modes of operations for the structurally distinct

species of probes are not different. Because the mode of operation among the structurally distinct species of probes is hybridization that occurs through known base-pair hydrogen bonding of purine-pyrimidine interactions (see response, pg. 3, lines 18-23 to pg. 4, lines 1-4). And that "as each type of probe could be labeled with an identical type of label, there is no showing that detection of labeled probes would differ" (see response, pg. 4, lines 1-4). Additionally, applicant traverses the species election requirement with respect to probe length. Because "an oligonucleotide probe of, for example, 5 nucleotides in length would have the same fundamental chemical structure as an oligonucleotide probe of 6 nucleotides in length (see response, pg. 4, lines 14-16).

The species election requirements are maintained because applicant did not state on record that the species of nucleic acid, polynucleotide, and oligonucleotide of the presently claimed invention are structurally and functionally identical, the hybridization reaction of the presently claimed invention is only due to purine-pyrimidine interactions, and the type of labeled use for detection in the presently claimed invention are identical. Further, Watson and Crick have argue that base pairing through hydrogen bond can occurs in ***only a specific way*** that is adenine pairs with thymine and guanine pairs with cytosine. Therefore, the species election requirements are maintained.

The requirement is still deemed proper and is therefore made FINAL.

5. Claim 40 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Specification

6. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code such as that found on pg. 25, line 8. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

7. Claims 14-20, 33-36, 39, and 41-48 are treated on the merit in this Office Action.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 14-20, 33-36, 39, and 41-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a written description rejection)

The instant claim 14 recites a method of identifying probes or analytes. The method step comprising labeling the probe or analyte with nanotube (Claim 14 (a)); and detecting the nanotube (Claim 14 (b) and (c)).

The instant claims recites a method of identifying probes or analytes. The method step comprising labeling the probe or analyte with nanotube (Claim 14 (a)); "binding" the probe or

analyte to a ligand (Claim 19), wherein the elected ligand is nucleic acid (Claim 20); and detecting the nanotube (Claim 14 (b) and (c)).

The specification disclosure does not sufficiently teach the method of identifying probes or analytes with carbon nanotube wherein the ligand is other than the elected species of nucleic acid. The specification disclosure does not sufficiently teach the method of identifying probes or analytes with carbon nanotube by just detecting the nanotube without hybridization of the probe.

The specification examples (pg. 25-26, Example 1-3) are drawn to a method of identifying a probe. The method steps comprises of labeling the probe with carbon nanotube; after the probe is labeled with carbon nanotube it is allowed to hybridize to the nucleic acid (ligand). Then the hybridized nucleic acid is sent to the detection unit wherein the probe is identified. The specification does not teach the method of identifying probes or analytes with carbon nanotube wherein the ligand is other than the elected species of nucleic acid. The specification also does not teach the method of identifying probes or analytes with carbon nanotube by just detecting the nanotube without hybridization of the probe.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

With the exception of the hybridization of the probe with carbon nanotube to the nucleic acid disclosed by the specification, the skilled artisan cannot envision the method of identifying

probes or analytes with carbon nanotube wherein the ligand is other than the elected species of nucleic acid. The skilled artisan cannot also envision the method of identifying probes or analytes with carbon nanotube by just detecting the nanotube without hybridization of the probe. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In *re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

In the present instance, the claimed method of identifying probes or analytes with carbon nanotube wherein the ligand is other than the elected species of nucleic acid (see the ligand list of Claim 20). The specification does not teach the method of identifying probes or analytes with carbon nanotube wherein the ligand is other than the elected species of nucleic acid. The specification also does not teach the method of identifying probes or analytes with carbon

nanotube by just detecting the nanotube without hybridization of the probe. Therefore, only the method of identifying probes or analytes with carbon nanotube wherein the ligand is nucleic acid, but not the full breadth of the claim method meet the written description provision of 35 U.S.C 112, first paragraph.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 14-20, 31-39, and 41-48 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: The ligand is a required component in the method of identifying the probes. As disclosed in the specification (pg. 25-26, Example 1-3), after the probe is labeled with carbon nanotube it is allowed to hybridize to the nucleic acid (ligand). Then the hybridized nucleic acid is sent to the detection unit wherein the probe is identified.

12. Claims 14-20, 31-39, and 41-48 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: The method step of binding the probe to a ligand is omitted in the method of identifying the probes. As disclosed in the specification (pg. 25-26, Example 1-3), after the probe is labeled with carbon nanotube it is allowed to hybridize to the nucleic acid (ligand). Then the hybridized nucleic acid is sent to the detection unit wherein the probe is identified.

13. Claims 19-20 and 41-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear if the nucleic acid of the elected species of "ligand" (Claim 20) is the same as the hybridization nucleic acid (Claim 41). To further prosecution, the nucleic acid of the elected species of "ligand" is considered to be the same as the hybridization nucleic acid.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 14-15, 19-20, 33, 41-42, and 45-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Massey et al. (US Patent 5,866,434).

Massey et al. disclose an assay method (method of identifying a probes or analytes) using functionalized carbon nanotubes (col. 40. lines 12-14). The assay methods include a DNA probe assay using carbon nanotubes (col. 40, lines 41-57). The method comprises 'the steps of: (a) forming a composition containing, (i) said sample, (ii) an assay-performance-substance which contains a component linked to a label compound capable of being induced to luminesce, and (iii) a plurality of functionalized graphitic nanotubes bound to an assay-performance-substance (refers to step (a) of claim 14); (b) incubating said composition to form a complex which

includes said functionalized graphitic nanotube and said label compound; (c) collecting said complex in a measurement zone; (d) inducing the label compound in said complex to luminesce by surface selective excitation (refers to step (b)), and (e) measuring the emitted luminescence to measure the presence of the analyte of interest in the sample (refers to step (c))' (col. 13, lines 9-31). Biotinylated ssDNA (the "analyte") bound to the avidin fibrils and was detected by the ECL of a complementary single stranded oligonucleotide ,which had been labeled (refers to claims 19-20 and 33) (col. 40, lines 47-57). The methods of the invention can be carried out in a static or flow-through mode (refers to claims 45-48) (col. 21, lines 65-67). The apparatus comprise of a light detection/measurement device and a pump to provide for fluid transport to, through and from cell (microchannel) (col. 22, lines 6-19). Therefore, the method of Massey et al. anticipates the presently claimed invention.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claims 14-20 and 31-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Massey et al. (US Patent 5,866,434) and Wohlstadter et al. (US Patent 6,140,045).

Massey et al. disclose an assay method (method of identifying a probes or analytes) using functionalized carbon nanotubes (col. 40. lines 12-14). The assay methods include a DNA probe

assay using carbon nanotubes (col. 40, lines 41-57). The method comprises 'the steps of: (a) forming a composition containing, (i) said sample, (ii) an assay-performance-substance which contains a component linked to a label compound capable of being induced to luminesce, and (iii) a plurality of functionalized graphitic nanotubes bound to an assay-performance-substance (refers to step (a) of claim 14); (b) incubating said composition to form a complex which includes said functionalized graphitic nanotube and said label compound; (c) collecting said complex in a measurement zone; (d) inducing the label compound in said complex to luminesce by surface selective excitation (refers to step (b)), and (e) measuring the emitted luminescence to measure the presence of the analyte of interest in the sample (refers to step (c))' (col. 13, lines 9-31). Biotinylated ssDNA (the "analyte") bound to the avidin fibrils and was detected by the ECL of a complementary single stranded oligonucleotide ,which had been labeled (refers to claim 19-20). The methods of the invention can be carried out in a static or flow-through mode (refers to claims 45-48) (col. 21, lines 65-67). The apparatus comprise of a light detection/measurement device and a pump to provide for fluid transport to, through and from cell (microchannel) (col. 22, lines 6-19).

The method of Massey et al. does not expressly disclose that the method comprises identifying one or more peaks in the optical emission spectrum of each nanotube.

Wohlstadter et al. disclose an assay method using carbon nanotubes (col. 12, lines 42-45) The assay method comprise of '(a) contacting one or more of a plurality of discrete binding domains, said plurality of binding domains (i) being immobilized on a surface of one or more supports, and (ii) being spatially aligned with and in proximity to a plurality of electrode and counterelectrode pairs, in which said contacting is with a sample comprising molecules linked to

an electrochemiluminescent label; (b) bringing an electrode and counterelectrode into proximity to said one or more of a plurality of binding domains; (c) applying a voltage waveform effective to trigger electrochemiluminescence at said one or more of a plurality of binding domains; and (d) detecting or measuring electrochemiluminescence' (col. 9, lines 61-67 to col. 10, lines 1-6). The assay includes DNA binding assay (col. 20, lines 51-67 to col. 21, lines 1-19; col. 55, lines 51-67). The method of detection includes 'detecting of sequential emissions or may be plural to detect and spatially resolve simultaneous emissions at single or multiple wavelengths of emitted light' (col. 26, lines 1-17).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the method step of identifying one or more peaks in the optical emission spectrum of each nanotube as taught by Wohlstadter et al. in the method of Massey et al. One of ordinary skill in the art would have been motivated to include the method step of identifying one or more peaks in the optical emission spectrum of each nanotube in the method of Massey et al. for the advantage of providing a rapidly and efficiently method to collect large amounts of data that can be stored, e.g., in the form of a database consisting of a collection of clinical or research information. The data collected may also be used for rapid forensic or personal identification. For example, the use of a plurality of nucleic acid probes when exposed to a human DNA sample can be used for a signature DNA fingerprint that can readily be used to identify clinical or research samples (Wohlstadter: col. 27, lines 35-43). Since both Massey et al. and Wohlstadter et al. disclose the assay method using carbon nanotubes (Massey: col. 40. lines 12-14; Wohlstadter: col. 12, lines 42-45).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
June 16, 2003

PADMASHRI PONNALURI
PRIMARY EXAMINER